DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC.
Jessica Andreshak
Director of Quality Assurance/Regulatory Affairs
3225 Gateway Road, Ste. 250
Brookfield, Wisconsin 53045

Re: K150180
Trade/Device Name: InTone
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI, HIR
Dated: January 26, 2015
Received: January 27, 2015

Dear Jessica Andreshak,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Statement of Indications for Use

510(k) Number (if known):

Device Name

InTone

Indications for Use

InTone is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of female urinary incontinence.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

7. 510(k) Summary

Submission Date

January 26, 2015

Submitter Information

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Device Information

Table 7.1 Device Information

Type of 510(k):	Traditional 510(k)
Common Name:	Pelvic Floor Muscle Stimulator
Trade Name (proprietary name):	InTone
Classification name:	Stimulator, Electrical, Non-Implantable, For Incontinence
	Device, Perineometer
Classification Regulation:	21 CFR 876.5320
	21 CFR 884.1425
Class:	Class II
Product Code:	KPI
	HIR

Legally Marketed Device for Substantial Equivalence

Table 7.2 Predicate Device Information

510(k)	Name	Product Code	Manufacturer
K110179	InTone	KPI	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA
K134020	InToneMV	KPI/HCC	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA

Device Summary

The InTone device includes three parts: an Insertion Unit, a Control Unit, and a Software Application for clinicians. Each of these parts are summarized below:

- The Insertion Unit includes an inflation pump and an inflatable probe. The inflatable probe is inserted into the vagina and the inflation pump is used by the patient to manually inflate the probe, ensuring a customized fit. Electrical stimulation is delivered via stainless steel electrodes on the inflatable probe to induce a contraction of the pelvic floor muscles. Biofeedback is monitored via a pressure sensor within the Insertion Unit which records changes in pressure related to volitional muscle contraction.
- The Control Unit includes user keys to initiate and control treatment sessions, and a visual biofeedback graph to encourage muscle re-training. The Control Unit is designed to record and store results of the electrical stimulation and biofeedback sessions for clinician review at follow-up visits.
- The Software Application is utilized by the clinician to program the Control Unit and display the results of electrical stimulation and biofeedback sessions. The Software Application allows the clinician to select and lock in the appropriate electrical stimulation level necessary to stimulate pelvic floor contraction.

Intended Use

InTone is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of female urinary incontinence.

Equivalence Comparison to the Predicate

Electrical muscle stimulation and biofeedback are the technological principles for InTone and the predicate devices. It is based on the use of the electrical muscle stimulator and/or biofeedback to strengthen the pelvic floor muscles and surrounding structures. The chart below summarizes the shared and different technological elements. The intended use, technology, engineering, performance and user interface for InTone is substantially equivalent to the predicate devices.

Table 7.3 Substantial Equivalence Comparison Table

Feature/ Function	InTone (K110179)	InToneMV (K134020)	InTone (New Device)	Comparison	Impact on Safety and Performance
Intended Use An explicit description of all clinical functions performed by the device. **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of male and female urinary and fecal incontinence.	InTone is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of female urinary incontinence.	Substantially equivalent	None

Feature/ Function	InTone (K110179)	InToneMV (K134020)	InTone (New Device)	Comparison	Impact on Safety and Performance
Primary Function	Delivery of electrical stimulation	Delivery of electrical stimulation Visual Biofeedback	Delivery of electrical stimulation Visual Biofeedback	Identical to InToneMV	None
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	Substantially equivalent	None
Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Patients with a pacemaker or implanted defibrillator require cardiac clearance before electrical stimulation is offered. • Patients with symptoms of active urinary tract infection, vaginal infections, localized lesions, or other undiagnosed symptoms. • Patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Patient has overflow incontinence caused by evacuation problems. • Patient has severe urine retention in the upper urethra or other symptoms of urine retention. • Patients with neurological deficiency that does not permit proper sensory perception of stimulation or complete denervation of the pelvic floor. • Patients with cognitive disabilities, i.e.; Alzheimer's disease or dementia. • Patients who are currently pregnant or attempting to get pregnant. • Patients with anatomical pelvic structures that do not permit proper and complete placement of the Insertion Unit. • Patients with active pelvic malignancy. • Patients with an intestinal clamp. • Patients should be 6 weeks post-pelvic surgery or vaginal childbirth. • Device should not be used for diagnostic purposes or critical patient monitoring. • Device is not (external) defibrillator-proof.	• Patients with a pacemaker or implanted defibrillator require cardiac clearance before electrical stimulation is offered. • Patients with symptoms of active urinary tract infection, vaginal infections, localized lesions, or other undiagnosed symptoms. • Patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Patient has overflow incontinence caused by evacuation problems. • Patient has severe urine retention in the upper urethra or other symptoms of urine retention. • Patients with neurological deficiency that does not permit proper sensory perception of stimulation or complete denervation of the pelvic floor. • Patients with cognitive disabilities, i.e.; Alzheimer's disease or dementia. • Patients who are currently pregnant or attempting to get pregnant. • Patients with anatomical pelvic structures that do not permit proper and complete placement of the Insertion Unit. • Patients with active pelvic malignancy. • Patients with an intestinal clamp. • Patients should be 6 weeks post-pelvic surgery or vaginal childbirth. • Device should not be used for diagnostic purposes or critical patient monitoring. • Device is not (external) defibrillator-proof.	Identical to InToneMV	None
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	Substantially equivalent	None
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	Identical	None
Power Source	4/5 AA nickel metal hydride battery	4/5 AA nickel metal hydride battery	4/5 AA nickel metal hydride battery	Identical	None
Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	Identical	None

Feature/ Function	InTone (K110179)	InToneMV (K134020)	InTone (New Device)	Comparison	Impact on Safety and Performance
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	Identical	None
Number of output modes	1	1	1	Identical	None
Number of output channels	1	1	1	Identical	None
Regulated current or voltage?	Regulated voltage	Regulated Voltage	Regulated voltage	Identical	None
Firmware controlled?	Yes	Yes	Yes	Identical	None
Automatic Overload Trip?	Yes	N/A	N/A	Identical to InToneMV	None
Automatic No-Load Trip?	Yes	N/A	N/A	Identical to InToneMV	None
Automatic Shut Off?	Yes	Yes	Yes	Identical	None
Indicator Display • On/Off Status • Low Battery	 Yes Yes	 Yes (via display illumination) Yes	 Yes (via display illumination) Yes	Identical to InToneMV	None
Waveform, shape	Dual phase, rectangular pulses	Dual phase, rectangular pulses	Monophasic, alternating polarity, square pulses	Substantially equivalent	None
Frequency • Mixed • Stress • Urge	 50 Hz - -	 - 50 Hz 13 Hz	 - 50 Hz 13 Hz	Identical to InToneMV	None
Pulse width • Mixed • Stress • Urge	 200 μs/phase - -	 200 μs/phase - -	 200 μs/phase - -	Identical	None
Time • On • Off	 20 seconds 10 seconds	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2 second no stimulation (repeating)	1 second at 50 Hz 2 seconds no stimulation 2 seconds at 13 Hz 2 second no stimulation (repeating)	Identical to InToneMV	None
Total Session Time	12 mins	Total: approximately 12 minutes • 2 minute volitional contractions • 5 minutes muscle stimulation • 5 minutes volitional contractions	Total: approximately 12 minutes • 2 minute volitional contractions • 5 minutes muscle stimulation • 5 minutes volitional contractions	Identical to InToneMV	None
Max output voltage (500Ω)	50 Vdc	50 Vdc	40 Vdc	Substantially equivalent	None
Max output current (500Ω)	100 mA	100 mA	80 mA	Substantially equivalent	None
Maximum phase charge (500Ω)	20 μC	20 μC	16 μC	Substantially equivalent	None
Electrode surface area	10.5 cm^2 x 2	2.5 cm^2 ± 0.5 cm^2 (x 2)	6.00 cm^2 ± 0.5 cm^2 (x 2)	Substantially equivalent	None
Max current density	9.5 mA/ cm^2	40 mA/ cm^2	13.3 mA/cm^2	Substantially equivalent	None
Max average power density (500Ω)	4.8 mW/cm^2	20 mW/cm^2	5.33 mW/cm^2	Substantially equivalent	None
Biofeedback	Air pressure, 0 – 2 psi	Manometric Air pressure, 0 – 2 psi	Manometric Air pressure, 0 – 2 psi	Identical to InToneMV	None

Feature/ Function	InTone (K110179)	InToneMV (K134020)	InTone (New Device)	Comparison	Impact on Safety and Performance
Dimensions	Control Unit: 4.88" x 2.38" x 1.07" Insertion Unit (overall): 12.2" x 2.5" x 4.0" Inflatable Probe (avg. inflated): 5.5" x 2.2" x 2.5"	Control Unit: 4.8" x 2.4" x 1.1" (+/- 1.0") Inflation bulb: 7.7" x 2.3" x 3.9" (+/- 2.0") Inflatable Probe (with handle): 4.8" x 1.0" x 1.5" (+/- 1.5") Tubing: Maximum 41" long	Control Unit: 4.88" x 2.38" x 1.07" Insertion Unit (overall): 12.2" x 2.5" x 4.0" Inflatable Probe (avg. inflated): 5.5" x 2.2" x 2.5"	Substantially equivalent	None
Control housing material	ABS plastics	ABS plastics	ABS plastics	Identical	None
Insertion material	Silicone, plastics	Silicone, plastics	Silicone, plastics	Identical	None
Tubing Material	NA	Silicone	N/A	Identical to InTone	None
Packaging or Expiration Dating	1 year for Insertion Unit	N/A	N/A	Identical to InToneMV	None
Sterilization	N/A	N/A	N/A	Identical	None
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical	None
Patient Interaction: Functions Controllable: An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.	Identical	None
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	None, programming can only be changed by clinician	None, programming can only be changed by clinician	Identical	None
Override	Yes	Yes	Yes	Identical	None
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical	None
Software Level of Concern	Moderate	Moderate	Moderate	Identical	None

The new InTone has the same internal electronics, stimulation waveform/algorithm, internal firmware, and external software application as the predicate InToneMV (K134020). The new InTone has the same patient contacting materials as the predicate InTone (K110179).

Testing Summary

As a result of the similar features between the new InTone and the predicate InTone (K110179) and InToneMV (K134020), this claim of substantial equivalence references the software verification and validation, electrical safety, and EMC testing performed on the predicate InToneMV, and the biocompatibility testing performed on the predicate InTone. New software verification and validation, electrical safety, EMC, and biocompatibility testing did not need to be performed to demonstrate the equivalent safety and effectiveness of this new version of the InTone.

Software Verification and Validation Testing:
Software verification and validation testing were conducted on the predicate InToneMV and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator. New software verification and validation testing did not need to be performed to demonstrate the equivalent safety and effectiveness of this new version of the InTone.

Electrical Safety and Electromagnetic Compatibility Testing:
Electrical safety and EMC testing was conducted on the predicate InToneMV. The device complies with the IEC 60601-1 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC. New electrical safety and EMC testing did not need to be performed to demonstrate the equivalent safety and effectiveness of this new version of the InTone.

Biocompatibility Testing:
The biocompatibility evaluation for the predicate InTone was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The inflatable probe on the Insertion Unit is considered tissue contacting for a duration of less than 24 hours. The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

New biocompatibility testing did not need to be performed to demonstrate the equivalent safety and effectiveness of this new version of the InTone.

Clinical Literature Review:
The clinical literature review, which is included to provide additional supporting evidence of InTone safety and effectiveness, consisted of a published article search and a MAUDE search. The published article search included documented evidence of the safety and efficacy of electrical stimulation for the treatment of female urinary incontinence. An appraisal of each article was completed as part of the search. The appraisal included an assessment of suitability of each article, a device performance assessment and a device safety assessment. The MAUDE search included reviewing risk associated with currently marketed devices classified as an "electrical muscle stimulator."

Risk Management Summary

InTone has been designed according to InControl Medical's internal procedures with traceability between the design inputs, design outputs verification and validation activities.

InTone has been evaluated for risks according to InControl Medical's internal procedures based on ISO 14971. The risks associated with InTone were reduced to as low as possible and the risk/benefit analysis was acceptable.

Conclusion

Both the InTone and the predicates are indicated for the treatment of female urinary incontinence. As a result of the similarities in design and construction between the new InTone and the predicates, the bench testing performed on the predicate InTone and InToneMV continue to support the safety and effectiveness of this new device version. The literature review further supports the use of electrical stimulation in the treatment of urinary incontinence in women. The InTone is substantially equivalent to the predicate devices.